DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGIC HEALTH

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE

Monday, August 26, 2002

***9:00* a.m.**

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C O N T E N T S

P R O C E E D I N G S

Opening Remarks

MS. HARVEY: Good morning. The National Mammography Quality Assurance Advisory Committee is called to order. We have a very busy schedule today so it will be important for us to keep to our schedule as we go. My name is Maryanne Harvey, for those of you who haven't met me as yet.

Dr. Finder will now give us our conflict of interest statement.

Conflict of Interest Statement

DR. FINDER: The following announcement addresses conflict-of-interest issues associated with this meeting and is made a part of the record to preclude even the appearance of any impropriety. To determine if any conflict existed, the agency reviewed the submitted agenda and all financial interests recorded by the committee participants.

The confl'ict-of-interest statutes prohibit special government employees from participating in matters that could affect their or their employer's financial interest. However, the agency has determined that participation of certain members, the need for whose services outweighs the potential conflict of interest involved is in the best

interest of the government.

Therefore, waivers permitting full participation in general matters that come before the committee have been granted for certain participants because of their financial involvement with facilities that will be subject to FDA's regulations on mammography quality standards with accrediting, certifying or inspecting bodies, with manufacturers of mammography equipment or with their professional affiliations since these organizations could be affected by the committee's deliberations.

These individuals are James Camburn, Nancy Ellingson, Alisa Gilbert, Maryanne Harvey, Melissa Martin, Linda Pura, Amy Rigsby and Drs. Miles Harrison, Jessica Henderson, Catalina Ramos-Hernandez, Debra Ikeda, Andrew Karellas, Daniel Kopans, Amy Lee, Etta Pisano and Donald Young.

Copies of the waivers may be obtained from the agency's Freedom of Information Office, Room 12A-15, of the Parklawn Building.

Several of our members also reported that they received compensation for lectures they have given or will give on mammography-related issues.

However, they have affirmed that these lectures were offered because of their expertise in the subject matter and not because of their membership on the committee.

We would like to note, for the record, that if any discussion of states as certifying bodies was to take place in any meetings of the committee, it would be a general discussion only. No vote would be taken and no consensus sought.

In the interest of getting as many viewpoints as possible, all SGEs, including state employees, would be allowed to participate in the general discussion so that all viewpoints could be heard.

In the event that the discussions involve any other matters not already on the agenda in which an **FDA** participant has financial interest, the participants should excuse him or herself from such involvement and the exclusion will be noted for the record.

With respect to all other participants, we ask, in the interest of fairness, that all persons making statements or presentations disclose any current or previous financial involvement with accreditation bodies, states doing mammography

inspections under contract to FDA, certifying bodies, mobile units, breast implant imaging, consumer complaints and mammography equipment.

MS. HARVEY: Thank you, Dr. Finder.

Introductions

Since we have four new members at this meeting--it is nice to see our new members and to see our returning members from last year--1 would ask that each one of us give a very short bio so that we can get more acquainted with each other's experience and background.

Dr. Pisano, could I ask you to begin?

DR. PISANO: I am Dr. Etta Pisano. I am the Chief of Breast Imaging at the University of North Carolina in Chapel Hill. I am a radiologist.

DR. YOUNG: I am Don Young. I am a radiologist, a professor of clinical radiology at the University of Iowa College of Medicine and practice at the hospital and clinics where I direct the breast imaging and diagnostic center.

DR. RAMOS-HERNANDEZ: I am Catalina Ramos with the National Breast Cancer Organization. We are a not-for-profit advocacy and counseling services for patients with breast cancer.

MS. RIGSBY: I am Amy Rigsby. I am the

Technical Director of the Rose Breast Imaging Center in Houston, Texas. I am a mammographer.

MS. MARTIN: I am Melissa Martin. I am a nedical physicist running a consulting practice in Southern California.

DR. IKEDA: I am Debra Ikeda. I am Director of Breast Imaging at Stanford University Medical Center. I am a radiologist.

DR. KARELLAS: I am Andrew Karellas. I am a medical physicist. I have been with the University of Massachusetts as of two weeks ago and now I have moved to join the faculty at Emory University in Atlanta.

DR. HARRISON: I am Miles Harrison. I am a surgeon by training. I am part of the Sinai Surgical Associates in Baltimore, Maryland and one of the designated breast surgeons at the Lapedes Cancer Center which is a Hopkins affiliate.

DR. FINDER: Dr. Charles Finder. I am a radiologist working for the Food and Drug Administration and I am also the Executive Secretary of this committee.

MS. HARVEY: I am Maryanne Harvey. I am with the New York State Department of Health. I am a section chief who is responsible for mammography

and also the Chairman of this committee.

MS. PURA: Good morning. I am Linda Pura. I am one of the clinical nurse coordinators for the Los Angeles County Breast Cancer Early Detection Program under the Department of Health California, Cancer Detection Section. I am also the co-founder and present President of the Los Angeles County Susan G. Komer Breast Cancer Foundation.

MR. CAMBURN: I am Jim Camburn. I am Chief of the Radiation Safety Section for the State of Michigan.

MS. ELLINGSON: I am Nancy Ellingson. I am a radiologic technologist and mammographer. I am with the American Society of Radiologic Technologists in Albuquerque, New Mexico. We represent about 100,000 radiologic technologist members.

MS. GILBERT: I am Alisa Gilbert. I am a seven-year breast cancer survivor. I work with Alaska Natives and American Indians. I am the Director of the National Native Cancer Survivor Support Network.

MS. HENDERSON: I am Jessica Henderson. I am an eight-year cancer survivor and I represent the Oregon Breast and Cervical Cancer Coalition.

DR. LEE: Hi. I'm Amy Lee. I am Assistant Professor of Community Medicine at Northeastern Ohio University's College of Medicine and Administrative Director for the Master of Public Health Program also located there. I am also a physician consultant for the local Breast and Cervical Cancer Program and, in my former life, before academia, I was OB-GYN.

MS. HARVEY: Thank you.

I will now ask Dr. Finder to talk to us about alternative standards.

Alternative Standards

DR. FINDER: I just want to give a little bit of background on approval for alternative standards. For those not familiar with this section of the regulations, FDA may approve an alternative to a quality standard that currently exists under Section 900.12 when the agency determines that, one, the proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace and, two, the proposed alternative is too limited in its applicability to justify an amendment to the standard or it offers an unexpected benefit to human health that is so great

that the time required for amending the standard would represent an unjustifiable risk to human health and also that the granting of the alternative is in keeping with the purposes of the statute.

Since our last meeting, the division has approved several alternative standards and these will be discussed by Dr. Roger Burkhart.

DR. BURKHART: I might begin by referring you to one of the documents that you were given in preparation for the meeting, the Modifications and Additions to the Policy Help Guidance System, No. 5. You will find the new alternative standards included within this document.

The first one, the first new one which we approved last September, is found on Page 57 of the document. It is entitled The Manufacturer's Software Modification of the Automatic Exposure Control, but really what it applies to is the testing which has to take place after such modifications occur.

Software upgrades or modifications are defined by FDA as being major changes in the system which means that, after they are to take place, there has to be a mammography equipment evaluation

conducted of the equipment and any problems that are found have to be corrected before the equipment is used on patients.

Also, the regulations require that this evaluation and the testing which is involved be done by the physicist on site. But the applicant for this particular alternative requirement made a convincing case that, in this particular situation, we can assure mammography quality if on-site testing is done under conditions of medical physicist oversight.

By medical physicist oversight, what we mean is that the physicist has to be consulted, but it is his or her decision as to whether they actually have to come on site to do the testing or whether somebody else can do the testing and send the results to them for evaluation.

As I said, the applicant for this standard made a convincing case that medical physicist oversight would assure quality in this particular case. ***So,*** for this specific software modification has given an alternative standard, and when it is applied to the units and the models which are listed in the standard, medical physicist oversight is an option for the facility.

The second newly approved alternative standard was reapproved last May as found on page 58, and it, too, refers to the testing, the testing conditions or how the testing is done after the nodification takes place.

Like the last one I just mentioned, it also started out as a request related to a specific software upgrade, but in this case, the justification was that the testing which would take place after this particular upgrade, was the same type of testing which is done routinely by the quality control technologist.

So, it was felt that if the quality control technologist is qualified to do this as part of the routine QA program, then, they should be able to do it after the software modification, and so it is to be done in conditions of medical physicist oversight.

But we got to thinking if it applies to this particular upgrade, it could also apply to any with that particular qualification, so we do have the authority to expand on requests, and we did that.

We applied this alternative standard to any upgrade or modification of the computer

software in which the testing afterwards is normally done by the quality control technologist.

So, if the manufacturer feels that the modification meets this particular standard, they need to consult with us, confirm with us that we agree with this, and if we do, then they can go ahead and this testing after this modification can be done under conditions of medical physicist oversight.

The third new alternative standard, which begins on page 60, is different in nature. It deals with the quality assurance program including the quality control testing, full field digital mammography units, again to be more specific, it deals with the time period for which the corrective actions can be taken if the testing reveals that there are problems with the system.

Now, in the case of screen-film systems, we were able, at the time of the regulations, to define two classes of test failures. There are those test failures which are significant enough that the problem causing them has to be corrected before the piece of equipment is used again on patients.

Then, there are those which for various

reasons mostly dealing with the fact that there are compensating methods, we can allow more time for the correction of the test failures for the problem causing the test failures, and the time which was set for that was 30 days.

For screen-film systems, as I say, we can make that distinction, but for full field digital mammography systems, which were still in the research stage at the time the regulations were being developed, we couldn't make such a distinction.

So, for full field digital mammography systems, and any other new modality that might appear in the coming years, we took a conservative public health safety position. We said that any quality control test that has failed, the problem causing the failure has to be corrected before the equipment can be used on patients.

So, this is what the regulations say, and, of course, the expectation is that eventually, if a technology like full field digital mammography, once it becomes fully established, eventually, we would be able to rewrite the regulations and make a similar distinction as we did with screen-film.

But to begin with then, we took this

position, but at the same time, we tried to make it clear to the manufacturers and also to any facility that has a full field digital mammography unit that if they feel that there are some of the tests that they can make a case that a 30-day correction period could be allowed for test failures of that test, they could always apply for an alternative requirement.

About two months ago, General Electric made such an application for their Senographe 2000D, full field digital mammography unit, and we approved that alternative on July 14th.

Basically, what this alternative does is divide the quality control tests of the 2000D into three general groups, and an important one as far as terms of the changes which are involved is the third group or the group which is labeled with the letter C.

These were tests, quality control tests of the 2000D, which were equivalent to quality control tests of screen-film systems for which the 30-day correction period was already allowed.

Some of them involved the exact same testing methods using the exact same action limits and even testing components which were identical to

the full field digital mammography system as in some of the screen-film systems, so they were than equivalent in that case, they were virtually identical.

The other tests were not quite as identical, but basically, for most of them, the only difference is that the measurements are done off of digital images rather than off of films as it would be in the case in screen-film systems.

So, it seemed logical then that if these tests already were allowed a 30-day correction period when problems are found, then, it would be logical to allow the same 30-day correction period for them with full field digital mammography unit, with the 2000D.

During this 30-day correction period--perhaps **I** didn't make this quite clear earlier--during this 30-day correction period, the facility continued to use the part of the system which failed the test, they wouldn't have to take it out of service.

The other two groups are the remaining tests, and these are still tests which, if they are failed, the component which failed the test has **to** be taken out of service until the problem is

corrected.

The only reason really for dividing them into two groups is to emphasize something which also exists in the screen-film area, and that is, it is only the unit or the part of the unit which fails the test which has to be taken out of service.

That may mean the whole system in some cases, but it may mean only part of others. In the case of the 2000D, the A Group tests are tests that the image acquisition part of the system, and so if these tests are failed, the facility may have to stop acquiring new images until the problem is corrected, but as long as the B Group of tests are passed which relate to the interpretation of images, they can continue to interpret old images.

The opposite is true, if a test in the B Group is failed, the facility may have to stop with the interpretation of images, but as long as the A Group of tests are passed, they can continue to acquire and store images for each interpretation.

So, then this alternative requirement applies only to the Senographe 2000D. As I mentioned, other manufacturers and facilities which own full field digital mammography units or the

manufacturers, have the option of applying for a similar alternative requirement and we will consider it and determine whether or not it can be accepted.

These, then, are the three new alternative requirements that we have accepted since the last NMQAAC meeting. I would be happy to answer or try to answer any questions that you might have on them.

DR. PISANO: What do the other manufacturers have to do, do they have to apply for the same thing to get, because obviously, this only applied to GE?

DR. BURKHART: It only applies to GE as you would expect as GE was the applicant. They would have to go through a similar process, and their lists of tests, depending upon their system, will be different. They might have different tests, more or less, and are different, that could be given a 30-day correction period.

DR. PISANO: Just as a comment, some of the things listed under Item C were probably added to the QC manuals of GE at least, and the other companies, because of the MQSA requirements for film. *So,* my prediction, I actually have two other

units myself, I have GE Fischer and a Fuji system at UNC, is that all these tests listed under Item C are also required by the other manufacturers.

So, it might expedite things a bit if a more general statement could be made about these particular tests rather than every company, I don't know what the process is, but we would be grateful, those of us who are using the equipment, if there could be a more expedited process for this.

I hate to shut down a machine just because one of these things that wouldn't shut down my GE unit, you know, if my Fischer unit had one of these problems, you know, before Fischer had the chance to go in and apply for it.

So, it would be nice if the FDA could make a more general statement about this, just as a user of the device.

MS. HARVEY: One more reminder. Before we speak, let us give our names for the record.

DR. PISANO: Oh, sorry. I am Etta Pisano from UNC/Chapel Hill. It is just a suggestion of making this more general.

DR. BURKHART: Roger Burkhart again. We thought about that at the time we were looking at the GE application. As I mentioned, we did expand

the second alternative requirement to be broader than the original.

We decided at this stage, though, that since there is still **I** guess not much of a consensus in general on the testing with the different models, that it would be best to take each one in turn, but once the ground is broken, obviously, you know, it makes it much easier for the people coming along behind if the tests are really the same, it would only be for any unique things that they might have that we have to look at further.

The process **I** might mention, the process for looking at alternative requirements, actually also is described in a general way, and, in fact, it is right after the listing of the three alternative requirements, the new ones, on page 62, and it basically involves when a request comes in, a staff member is assigned to evaluate it.

Sometimes we see right upfront that more information is needed, ***so*** the staff member will ask for it, but if it looks fairly complete, then, we form a committee to look at it and evaluate it.

The committee tries to come up with a consensus, a recommendation being either to approve

or disapprove or to ask more information, and then it goes to the branch chief of the Accreditation and Certification Branch, which is the branch responsible for this, to agree or disagree, and then it goes to the division director for final decision.

So, the process is not really complicated and, as I said, once the ground has been broken in that area, it can go fairly fast.

The other point I guess I should mention, too, is that a facility can apply, as well as a manufacturer, so you do not have to wait for the manufacturer to take action to make the case.

MS. HARVEY: Any comments from our health physicists? Ms. Martin or Dr. Karellas.

MS. MARTIN: These standards are fine with me.

DR. KARELLAS: I agree with Melissa. The only thing I am a little apprehensive is that physicists just have to watch closer since different manufacturers have different requirements, so which is okay, that they can do it. Physicists practicing out there are very much into that. It just will add a little bit on their time for it. That is my only concern, but I am sure

they can do it.

MS. HARVEY: Thank you.

DR. BURKHART: Thank you.

Open Public Hearing

MS. HARVEY: Now, we are moving into the open public hearing aspect of our meeting today.

We have comments on quality control for full field digital mammography from Ken Crocker, who is Director of Marketing, Product Planning for the Fischer Imaging Corporation. Welcome.

MR. CROCKER: Thank you. My name is Ken Crocker and I very much appreciate this opportunity to address the committee on what I think is becoming a more important topic as time goes on.

As you all are probably becoming more aware, digital mammography has reached a greater degree of acceptance throughout the U.S., and I think is becoming more of a standard operating practice with probably well over 300 systems already in place throughout the country.

[Slide.1

There is I think a few issues developing as this acceptance has increased, and I thought it would be important to bring to the attention of this committee some of the issues that I think

apply to not only the manufacturers, but to the accrediting bodies, the **FDA**, and, of course, most importantly, the actual users of the equipment, as well.

We are in a situation right now that is rather unique, because when the regulations were really originally developed, of course, digital mammography was basically only a gleam in the eye of most people, but, in fact, we have reached that point that things need to happen now for it.

Because of that, the original regulation only stated that the Operator's Manual from the manufacturer should be followed as the appropriate quality control procedure. That is going to result in delay in providing oversight to users of the full field digital mammography system.

While it may be true that the **FDA**, as part of the **PMA** process, does review the Operator's Manual, and, of course, I think they do a fine job of that because they are the same people that are reviewing the proposed quality standards that certifying and accrediting bodies would propose, so I think we should be confident that they are doing a good job in that area, but nonetheless, it provides only a limited amount of oversight.

Once the **PMA** has been approved, the manual is in use, FDA will look at quality control charts after six months of use from a facility, but that is kind of the end of the process right there, and I think we want to get to a point where we have uniformity and standards.

So, basically, I will show you what the proposal is, but the issues today, there is a lack of uniformity because you do have each manufacturer proposing their quality standard, and there is limited oversight because it is primarily that review that happens as part of the **PMA** process.

Dr. Burkhart described the approval of alternate standards process. Certainly, you know, I think it has its place, but overall it would only be a stopgap measure in this particular instance since we are looking at a complete new set of standards for digital mammography, and I don't think we could rely strictly on that to address all of the needs.

[Slide.]

So, why does this issue linger? Obviously, hopefully, it hasn't lingered too long, but right now for us, as manufacturers, there is not a tremendous amount of incentive to

standardize.

Once we get through that process, which is challenging unto itself, we feel pretty confident that we have produced a reasonable quality control approach, and unless there is some really undue needs, we would prefer to just keep things running, because we want to be able to meet all of our customers' needs.

The MQSA Reauthorization Act of 2002 is not going to substantially change the landscape, I don't believe, at least in the last versions I have seen of it, that it addressed any of the issues that we are talking about here related to full field digital mammography.

The approval of alternative standards doesn't address the needs of accrediting bodies, as well. The accrediting bodies need to be able to get more involved with this process of controlling digital mammography.

[Slide.]

The proposal is to charge the FDA and accrediting bodies with development of these uniform standards, and to encourage their cooperation. I know we will be hearing from Dr. Chakrabarti this afternoon on that, and I know

there have been starts into this area, but I think there needs to be more urgency applied given how rapidly the acceptance is taking place with digital mammography.

We need to charge the FDA and the accrediting bodies to seek guidance from industry. Certainly, individual manufacturers are interested and willing to participate, and then NEMA, which, of course, is an industry group, also has started efforts in that area, as well, and would be more than happy to participate in doing that.

Our third point would be that FDA should allow accrediting bodies to accept the Manufacturers Manual for accreditation on an interim basis, and this would allow the transfer of responsibility over to the accrediting bodies, so that they could start becoming involved in this process. As of today, you know, they don't really have any sort of regulatory capabilities in that area.

[Slide.]

Charging the accrediting bodies with simplification and uniformity as a longer term goal, would also then follow with that, but at least we would have that immediate knowledge that

the Operators Manual is available and accepted by the accrediting bodies and the **FDA**.

Eliminate the requirement to maintain a film-screen system. **As I** mentioned, the review of the manuals is already carried out by a very respected group of individuals at the **FDA**, that are also responsible for the oversight of film-screen certifying and accrediting efforts.

If they are capable of doing that, I would expect they would be applying the same degree of rigor to digital mammography, and believe, in fact, that they have, so this requirement of maintaining a film-screen system, I think imposes an unnecessary burden both on users of the systems, as well as the entire community.

Lastly, getting to Dr. Pisano's point about why don't we just do this for all manufacturers, this synchronizing of tests that allow 30 days for corrective action, certainly, we agree and support that position.

Tests that are as common as repeat analysis, **I** know from our standpoint we tried to make things as simple, straightforward, and consistent as possible for users of our system so that they wouldn't have to completely rethink the

process of how they do a repeat analysis, for example

I think that the FDA should be charged with developing that uniform standard rather than waiting for either a user or a manufacturer to come to them. We actually did go to the FDA over a year ago with a similar request to what had been made for the GE system, but it is a rather challenging process to get through.

I mean I am not blaming anybody for what happened there, but I would just say that from my standpoint, I think it would be better for all of us if the FDA could take a proactive stance rather than a reactive stance to requests for these kinds of changes.

That is all I have prepared. I just want to thank you again for the opportunity to address the committee and appreciate your efforts to provide the best quality mammography for our community.

MS. HARVEY: Thank you, Mr. Crocker.

Any questions? Yes.

MR. CAMBURN: Jim Camburn from the State of Michigan. I think I have one question for you related to one of the things you commented on,

eliminating the requirement to maintain a film-screen system.

Are you suggesting, then, that the facility would not have any film-screen unit at the site where they would have **a full** field digital machine?

MR. **CROCKER:** Yes. Let me explain a little bit about what the requirement is today. The requirement today is that there is at least one film-screen system within a particular FDA jurisdiction that is under the supervision of a particular radiologist who has responsibility.

They don't have to be at physically the same location, you could have one at a hospital and then you could have a digital at an off-site facility, and as long as there was one film-screen present at one of those two locations under the jurisdiction of a particular supervising radiologist, that would be acceptable.

But we see it all the time now that there are situations where different groups of physicians want to become involved with digital mammography, they have the experience, they are willing to do the quality control that has been approved and recommended by the FDA, but they do not want to

invest in having a film-screen system, as well.

In fact, they have no intentions of using the film-screen system, but because of the way the regulations are today, they will go out, they will buy a film-screen system, they will do the absolute minimum to maintain the accreditation of that system or certification of that system, and therefore, I don't think it is really accomplishing much.

I think we are better off letting them focus on the quality control of the digital system that they really intend to use.

MR. **CAMBURN:** We see this from maybe a slightly different perspective because we have a number of facilities that have one digital unit and one film-screen unit, and they seem to use them differently, at least some facilities do. The digital full field mammography machine has a relatively small image receptor compared to the larger film size that you can get with film-screen imaging.

What they do, they will--average size patients might fit fine with the digital image receptor, but larger patients would require two exposures for each projection, and it kind of

doubles the patient dose in the area that the x-ray beam overlaps.

So, from a radiation dose point of view, isn't it better to have the ability to do both types of imaging?

MR. CROCKER: I certainly appreciate and agree with what you are saying. With the full field digital mammography from Fischer, it has a larger field of view, and therefore, in fact, the larger field of view is 21 by 29 cm, so the percent of the population that would require a multiple stitching together of images is no greater than what would be required under a film-screen system.

So, for our particular equipment, we don't see that problem, but I certainly can understand where you might be concerned about that from a radiation dose standpoint with some other systems that are available in the marketplace.

MS. HARVEY: Any other questions?

DR. **PISANO:** **I** just have a follow-up comment. **I** actually think from a public health viewpoint, in terms of getting digital out to remote areas where the images could be beamed back **to** a central site for interpretation, it makes a lot of sense to not require the film mammography,

because you are probably limiting access to remote areas, if they are going to use digital, they also have to have a film mammogram unit.

So, I would agree with his comments that he made, that we would like to move this process along, I would like to see it moved along, so that it is more standard and that the film mammography isn't required.

MS. HARVEY: Thank you.

Dr. Finder.

DR. **FINDER:** We have one comment that came in, and the person who submitted it would like me to read it into the record. It is a written statement from Pamela Gormley, who is a mammography supervisor at Epic Imaging in Oregon.

Her statement is as follows:

The following is a mammography item that I believe the FDA needs to expedite the changes on. We have had two of the new **FFDM** GE 2000D digital mammography units since October 2000. However, the FDA says we still have to have a film-screen unit on the premises, plugged in and ready to use, even though a film-screen is outdated technology.

This is approaching two years. This is wasting both their resources and space for

mammography. We would have replaced that unit with newer technology if the FDA allowed it. We also have to maintain a film processor that we don't want or need.

All of the quality control tests that we do on the digital units show that they have much better detail on the phantom image and on patients, with one-third less radiation per view than the former state-of-the-art film-screen system that we have.

Our film-screen combo is the detailed Fuji AD-M fine screen with Fuji AD-M film, dedicated Kodak M-35A processor with White Mountain chemicals, 135-second processing at 95 degrees, using GE Senographe DMR bi-metal tube mammogram machine maintained by **GE** service, but it cannot begin to compare with what we see with the digital system.

Please get this changed immediately, so that we can provide the best medical care to our patients without wasting money.

MS. HARVEY: Thank you.

DR. FINDER: **I** would like to add that we are going to have some more talk about this entire issue later on in the afternoon.

MS. HARVEY: We are a little ahead of schedule, so if Michael Divine is prepared, we will move on to the open committee discussion.

Michael is going to talk to us on Overview of MQSA Inspection Findings and Current Inspection Follow-up Actions.

Overview of MQSA Inspection Findings and Current Inspection Follow-up Actions

MR. DIVINE: My name is Mike Divine and I work in the Inspection and Compliance Branch in the Division of Mammography Quality and Radiation Programs.

[Slide.]

My talk today is, appropriately enough, on inspections and compliance.

[Slide.]

I will be going over a summary of problems that we have found during our annual inspections and also an overview of the various actions FDA might take when facilities have serious problems or failed to correct these problems.

[Slide.]

For the inspection data, my talk will cover the last two complete fiscal years for FDA data plus most of the current fiscal year which

will end on September 30th. While the data for this year is not complete, I think we have enough data for comparison purposes.

[Slide.]

While most people here today are probably familiar with our inspection levels, I thought a slide was needed for those who might not be familiar with them.

Level 1 is the most serious and could result in FDA action if not corrected.

Level 2 is less serious, but still significant enough that a facility is required to respond to FDA with their corrective action.

Level 3 findings are considered minor.

[Slide.]

As you can see from this first slide, facilities continue to improve and the overall rate of problems has been declining, which is very good news.

'While this slide only shows two full fiscal years plus most of a third, if we extended these data back to 1995, when we started inspections, the trend would be even more pronounced.

[Slide.]

This slide shows Level 1 problems with personnel. While the chart shows a jump for some categories in 2001, the small numbers compared to the overall percentage of inspections doesn't indicate that this is a real problem. For the medical physicist, the number of violations has all but vanished.

I would mention at this point that this data represents inspections ***of*** approximately 9,500 facilities.

[Slide.]

Processor QC problems continue to be a source of problems, but these numbers are also going down. The same is true for missing phantom QC data.

[Slide.]

On this slide, as opposed to the previous slides which showed data for the facility QC testing, these data come from our inspector testing. The number of violations for phantom image is very **small**, as are data for processor speed. Fog values are somewhat higher, although these numbers have been declining.

[Slide.]

For the medical physicist surveys and

mammography equipment evaluations, the most common problems are overdue surveys, surveys missing specific tests or data, and failures to do evaluations on x-ray units and processors. These numbers are also declining.

[Slide.]

For interpreting physicians, the number of facilities cited for initial training or experience remains low. For continuing education and experience, the numbers are greater, but are declining.

[Slide.]

For radiologic technologists, we see a similar trend. The jump in continuing experience is probably due to this first thing checked in 2001. We expect these numbers will decline in the years to come.

[Slide.]

For medical physicists, the small number of facilities cited exaggerates the difference between the years. The missing bars for 2002, under the initial requirements, is due to no facilities being cited, as with the technologists, checking on the continuing experience is a relatively new assessment.

[Slide.]

For medical records, a lack of an appropriate assessment category on mammography reports dominates the problems, however, we have seen a substantial drop in the numbers in just three years.

[Slide.]

This chart shows some other requirements we check during inspections. The problems with x-ray units has dropped to almost nothing. For our first inspections with complaint and infection control procedures, the drop in the number of facilities with these problems has dropped dramatically.

[Slide.]

For the medical outcomes audit, only a small number of facilities still have problems. The last three sets of bars here reflect requirements only being checked in the last two years. As with some of the other cases like this, we expect these numbers will go down with time.

[Slide.]

This last slide from our inspection data shows a number of facilities that had at least one problem during their inspection for not having

complete documentation for their personnel.

[Slide.]

Moving away from the inspection, the next few slides will focus on the various options **FDA** has when facilities have continuing problems complying with our regulations.

[Slide.]

These types of actions include a follow-up inspection, additional mammography review, patient and physician notification, which is actually a follow-up action in case the additional mammography review shows problems, a directed plan of correction, civil money penalties, suspension or revocation of a facility's certificate, an injunction, which is actually a court order that would shut the facility down.

[Slide.]

When facilities fail to meet specific requirements, we may need to reinspect the facility to see if it has corrective problems. Most of the time, these inspections only focus on areas where the facility has failed in the past.

[Slide.]

Additional mammography review is a review of mammograms and/or mammography reports to

investigate previous or ongoing clinical problems at the facility. The purpose of the **AMR** is to look for serious problems where patients and physicians need to be notified. If there was a serious risk, there could be a possible patient and physician notification.

[Slide.]

For additional mammography review, we generally select certain types of issues that we think we want to do an **AMR**. One we do which is the most common although it has been significantly declining the last few years is we find a phantom image problem that is at Level 1 during an inspection, we will do an **AMR**.

We could do one for an interpreting physician that would fail to be qualified. Clinical image quality problems would be an obvious one. If there was an overall failure in the quality assurance program at the facility, that could trigger one, and we have done a few for fraudulent recordkeeping situations.

[Slide.]

The extent of an **AMR** could range from a few films to a larger sample. Our most common reason for **AMR**, as I mentioned, is Level 1 phantom

failure. A larger sample is usually needed if a smaller AMR shows serious problems or the problems at the facility to make a smaller review inappropriate.

[Slide.]

When an AMR shows serious problems, FDA would send the facility a letter requiring the patient and physician notification. These letters outline options referring physicians and patients have, such as getting their mammograms reread by another interpreting physician or getting a new mammogram. The letters are written in plain language, avoids using complicated jargon with patients.

[Slide.]

A directed plan of correction is a regulatory action FDA may take that imposes additional requirements on the facility. The goal of the DPC is to force the facility to perform mammography in compliance and allow FDA to easily monitor this performance.

Under a **DPC**, the facility is usually required to send FDA copies of records on **a** monthly basis and are subject to additional inspections to check on their performance.

[Slide.]

For more serious problems, FDA may suspend a facility's certificate. Once a certificate has been suspended, the facility can no longer perform mammography. In most cases, facilities are usually given a hearing prior to the suspension, however, FDA may suspend prior to a hearing if there is a serious risk to human health or other substantial violations.

[Slide.]

A last list of the remaining options that FDA has is rather than shutting a facility down, FDA may opt for charging a facility civil money penalties, and this could be up to $10,000 per violation or per day.

We could also revoke a facility's certificate, which is equivalent to suspension, however, once a certificate has been revoked, the owner or operator of the facility cannot own a mammography facility or operate a mammography facility for at least two years after the revocation.

[Slide.]

Lastly, if everything else fails and we feel that we have to go to court, we have the

ability to use an injunction which actually closes the facility down through a court order.

[Slide.]

In closing, this table shows the number of times FDA has taken specific regulatory actions based on problems occurring at facilities.

That concludes my talk.

MS. HARVEY: Thank you.

DR. PISANO: I have a question.

MS. HARVEY: Yes, Dr. Pisano.

DR. PISANO: Is this in the history of enforcement of MQSA or is this one year?

MR. DIVINE: This is the entire program.

DR. PISANO: And what is the denominator like 900-plus facilities per year times 8 years, something like that?

MR. DIVINE: Well, we inspect about 9,500 facilities.

DR. PISANO: That is what I meant, 9,500 times about 8 or 10 years?

MR. DIVINE: Yes.

DR. PISANO: So, it is 95,000 facilities, and these are the numbers, something like that, is that right?

MR. DIVINE: Yes.

DR. FINDER: I would want to add that this represents actions taken by FDA. This does not include actions taken by the State, and in several cases or many cases, the State has taken action before we have, and in that case, we don't pursue it any further, so it is not the total number of facilities that ran into problems.

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: You mentioned something about that the equipment-associated problems are something like very few or next to nothing, which is very encouraging, but I would like to comment for the public and for the lay press, because often we read about that there are no problems with the equipment or it has nothing to do with the equipment.

The reasons that inspectors find very few problems with the equipment is that equipment is very well maintained. We find problems with the equipment all the time routinely. Almost on a weekly or monthly basis, technologists will walk in and will find problems with a processor, on occasion with the automatic exposure control, they typically call service or physicist depending on the situation, and the problems are taken care of.

So, this is why you don't see the problems. I am sure you know that, but the public perhaps doesn't understand that.

MR. DIVINE: That is a good point. We only go in once a year to do the inspection, and when we look at the equipment, basically, we find that there was a problem, but it has been fixed. It certainly is not something that shows up during the inspection.

I would also point out that as the years have gone by, a lot of equipment that had problems and couldn't be maintained has been replaced or repaired to where it can meet the requirements.

MS. HARVEY: Dr. Lee.

DR. LEE: Amy Lee. I was wondering if you ever analyzed your data for specific trends, like geographical areas that tended to have more violations or specific kinds of equipment, and if you have, have you noted any kinds of trends or clusters.

MR. DIVINE: I am not aware if we have done any geographic types of analyses.

MS. HARVEY: When we look at the Level 1 phantom image violations, would you talk to us a little bit about the scores that that might

represent, what is passing and what scores would be considered to be a serious violation, is it triggered immediately after below 10?

MR. DIVINE: The criteria we use for phantom image, we have two, Level 1 and Level 2. Level 2 is where it fails at the accreditation body's limit, which all the accreditation bodies use the same values, which are 4-5ers, 3 speck groups or 3 masses. If any of the objects go below any of those, it's at least a Level 2.

Now, our criteria for Level 1 is if it goes below 3, 2, or 2, which is one unit below the criteria. So, we do have a certain number of Level 2 phantom failures, and those are higher than a Level 1, but even those are not very high.

MS. HARVEY: Equipment has become much better at resolution over the years. Is there a debate about raising the image score?

MR. DIVINE: I am not aware of one. I have heard some people mention that, but there has been no urge for us or, as far as I know, the accreditation bodies to raise the values, but it is possible that there has been, I am not aware of it.

MS. HARVEY: Dr. Young.

DR. YOUNG: Don Young. Have you compared

your data with the States that are accrediting bodies and certifying bodies that had the data required relative to the inspections?

MR. DIVINE: Not that I am aware of.

MS. HARVEY: Dr. Young, do you have any data?

DR. YOUNG: No, I don't personally.

MS. HARVEY: Any other questions, comments?

Thank you.

MR. DIVINE: Thank you.

MS. HARVEY: It's time for a break. It's about 5 minutes of 10:00, perhaps 15 minutes, back at 10 minutes after 10:00. Thank you.

[Break.]

MS. HARVEY: Dr. Finder will provide us with information on Good Guidance Practices and Directions for Discussions on MQSA Guidance under the Final Regulations.

Dr. Finder.

Good Guidance Practices and Directions for Discussion of the MQSA Guidance under the Final Regulations

DR. FINDER: Before we begin our discussion of final regulation guidance, I would

like to briefly explain the procedures that FDA is following as it develops new guidance.

In response to public comment regarding the use of guidance documents, FDA held an open meeting on April 26, 1996, and on February 27, 1997, they published a federal notice outlining the steps the agency needed to take prior to issuing guidance.

In brief, it stated the following. Guidance has to be developed in an open manner that permitted input from the general public and the regulated industry. In most cases, new or controversial guidance had to allow for such input prior to its implementation.

While the statutes and their associated regulations were binding and enforceable, guidance was to represent a way or ways of meeting the regulations, but other ways would be acceptable as long as they met the requirements of the underlying regulations or statute.

Before we begin our discussions, I would like to emphasize the following. We are here to discuss the proposed guidance, not the underlying regulations. The regulations have already gone through their own extensive approval process and

while they are subject to future change, the purpose of today's meeting is to address the proposed guidance.

When you hear or see words like shall require or must, they refer to the underlying regulation, whereas, the words should, may, or recommend refer to the guidance. I also want to add that since the beginning of the program, we have issued a large amount of guidance to help facilities meet the underlying regulations.

This material, this guidance has been compiled into what we call the "policy guidance help system," which is a computerized search engine that is now available on the Internet to aid facilities in their compliance with the regulations.

There is probably about anywhere from 5- to 700 pages worth of guidance encapsulated in that search engine and what we are in the process of doing right now is going through all that guidance to update and revise it.

One of the documents that you have, which is Modification Document No. 5, is the first in that series where we are actually going page by page through all the previously issued guidance to

update and add material as appropriate.

So, with that said, I think that probably the first item that we would like to talk about is the issue of the agency automatic exposure control.

With that said, I guess we are done with AEC.

[Laughter.]

DR. FINDER: Let me give a little bit of background. We did send out a letter to the committee for them to look at prior to the meeting, and basically, this raised several issues about testing of the automatic exposure controls in some of the newer equipment that have multiple different configurations and submodes.

If anybody would like to start the discussion on that, I would appreciate it, otherwise, we are going to have a lot of time between now and lunch.

MS. HARVEY: Yes, Dr. Karellas.

DR. KARELLAS: At least I would like to start in one area of the AEC issues. There are certain systems that they may have various modes and medical physicists may be evaluating modes that they may not be actually used by the facility.

My own view is that there should be no

need to test every available mode of a complex AEC system if the facility does not intend to put it to use, and a facility should decide as to what they use, and that should be tested.

Now, I understand that in real life, a facility will start with something and perhaps a month later, they will decide that they need to use another mode, and that will happen. Although it may be not a problem for a physicist to test these two or three modes and have that, but if they are far more complex than that, and there are too many combinations, it may be unrealistic to be testing all these modes.

Then, the physicist could come back and reevaluate the system a few months later if that had to be, but I am not suggesting that the physicist should evaluate the AEC every time every minor modification is made, and the way it is used or some very minor repair.

I am saying that it should be tested only if there is a very substantial departure from what the system was initially tested.

MS. HARVEY: Ms. Martin.

MS. MARTIN: This is Melissa Martin.

I am the other medical physicist on this

panel. Obviously, what we are discussing affects what Andrew and I do the most. As a consulting physicist, just to put this in perspective, I obviously provide the medical physics services for, at this point, around 150 facilities, which covers around 250 mammography units on an annual basis.

We have many of the high-level, multi-mode, multi-target, multi-filter units in our practice. We have made great strides to test what I have considered all the clinical modes used for each one of these units when we go on site the first time.

In Southern California, I cover an area I call Southern California. I cover sites that are about 300 miles away. It is to my benefit and the facility's benefit to make these measurements when I go out there initially. That is why, as Andrew said, I try to cover all what is going to be called clinically useful or possible clinically useful combinations.

For those that use, as an example, the GE DMRs, I don't have any facilities that use the dose node on a 2-cm breast, so it makes no sense to require the physicist to test the dose mode for a 2-cm breast.

i think we do need to set an understanding here of what is clinically useful and what the physicist would be expected to test. Some of the newer units, the low radium 4's, it is not even possible to test at the low kVp's or the high kVp's for thin breasts, because the grid doesn't have time to move.

So, if you technically looked at some of what is proposed, it can't be. The other factor is how much time are we taking a facility down. We do impact the access to people to get mammography. If we go in to perform our measurements, we are typically in a room somewhere between 4 and 6 hours.

That is 4 to 6 hours that room is out of service and available for serving patients, and I think we have to be aware and very careful not to set measurement criteria that is not clinically relevant, but which will also add cost to the facility and decrease the amount of time that the patients can be examined.

DR. KARELLAS: Melissa put that very nicely. I think the vast majority of medical physicists feel that way.

MS. **HARVEY:** What percentage of the time

that you are testing the equipment do you think the AEC testing would involve? Is it a major part of the testing?

MS. MARTIN: At least 25 percent currently.

MS. HARVEY: And there are no surrogates, there aren't any simple tests that we can go to that would be representative of larger--

MS. MARTIN: I am saying it's 25 percent to do what I have been considering the clinical modes. If one of the discussions was pursued here that I had to test every kVp in every mode, you are adding at least 2 to 3 hours of testing, so you are roughly adding somewhere between 3- and $500 of additional cost and another 2 to 3 hours of time out of the room.

MS. HARVEY: Plus your time.

MS. MARTIN: Yes.

MS. HARVEY: Any other comments about AEC testing?

DR. FINDER: This is Dr. Finder again. I think you framed the issue. Now, we have got to get down to some of the specifics, and we did ask a couple of questions in the document that went out. We would kind of like some guidance on what you

think that reasonable testing is under the various scenarios.

The first issue that we talked about here is, as we have said, the current requirement is that a mode or configuration needs to be tested prior to clinical use. There are two different areas where that could occur. One is at the initial evaluation called the mammography equipment evaluation, and the other is during the annual physics survey.

The requirements in the regulations are slightly different for those two types of testing. One of the issues that has been brought up is, is it enough to test just all the modes and configurations at the initial mammography equipment evaluation, and then do something lesser of not possibly all the clinical modes at the annual survey.

This is one of the issues that we would appreciate the committee's guidance on.

MS. MARTIN: I will just respond and again this is where I am coming from. I basically use Alternative Test No. 2, which conforms to the ACR's suggested forms that are available in the latest QC Manual for the physicists.

That test I perform annually on all the modes with every machine. I personally have not skipped any of them, so I don't have any feel for what percentage of people typically only test in the contact mode. I always test the mag mode.

DR. KARELLAS: I always test the mag mode and most people I know test the mag mode, because we go pretty much by the ACR guidelines, so we use that as a guide, and we may make one or two additional measurements for other things that we feel might be necessary. That is what we go by.

MS. HARVEY: Does that help you, Dr. Finder? No?

DR. FINDER: Well, it partially addresses some of the issues, but we also have the concept of these units that have multiple different AECs. As has been brought up, some of these AECs are not used over the entire 2 to 6 cm range.

The regulations, however, say that the AECs have to be tested over that range, and we have some situations where a facility may say, well, we never use the 2 cm range for this type of submode of AEC, but we do use it at 4 and 6. Well, how is that going to be tested?

We also have the issue of a facility that

says they are going to use one submode at 2, another submode at 4, another submode at 6, what is the appropriate testing under those types of scenarios, do you just look at those three individual submodes at those levels, or do you require each one of those submodes to be tested at 2, 4, and 6?

These are some of the questions that have come up, and how do you deal with those kind of situations.

MS. MARTIN: What we have made the choices, if they are clinically using it, in other words, again, go back to the AOP contrast, the GE DMR has three different modes, well, actually several different modes, but three automatic modes AOP, which is contrast, standard, and dose.

Typically, what Dr. Finder is saying is a 2- or 4-cm breast would be examined in the contrast mode, 6 could be either contrast or standard. I typically test 2 and 4, I don't test 6 under contrast unless the facility says that is what they use. A standard, I typically do 4 and 6, I don't do 2 unless the facility says that is what they use.

I really do think you have to look at what

the facility is using, but if those modes are set up and cross with each other, that basically is your test. I think it is crucial that each mode be tested at least on some thickness to verify that you are tracking between modes. I don't find it mandatory that you test every thickness on every mode.

MS. HARVEY: So, if you are testing a unit and you look at either the 2, 4, or 6, and it is working properly, can you presume that it would be working properly at the other two thicknesses that you are not testing, or do you actually have to do each thickness?

MS. MARTIN: I have not found a problem. If it is working properly in the mode for which it is pretty much designed to work in, I have not found a problem with it tracking between the other nodes, but certainly I am not the only one performing these measurements.

Dr. Karellas.

DR. KARELLAS: We actually test at higher thicknesses than 6, but it is not a requirement, but we just do it because we want to see how the machine works, and we just draw a line there, so if it deviates, and sometimes they do, that then we

tnow at least that we have bracketed for the requirement.

Usually, the deviation may be very nominally below or above what the requirement is, but we know that the deviation is not really against any regulations, state or federal, but we are aware of it. If we see something and we need to adjust it, at least we know.

MS. MARTIN: One of the more crucial items as far as time testing is for those units that are now out there, that have individual detectors, there is one manufacturer that has seven or eight separate detectors, independent detectors.

I think the more crucial time thing is I have found it and what I have been doing is doing the full set of tests on one of the detectors and then cross-checking all the other detectors for the 4 cm breast. I have found that to be sufficient. I have not been testing all eight detectors for every target filter for every one.

I think again, as long as you are making a reasonable attempt to verify at typically the 4 cm thickness, that your detectors cross with each other, that should be considered an acceptable test.

MS. HARVEY: Dr. Pisano.

DR. PISANO: Isn't it true--this is a question for the physicists--isn't it true that if there were a problem with one of the **AECs,** for example, in that eight system, it would be obvious in the clinical images?

Wouldn't it be that it would be either too light or too dark over a certain region of the breast, **so** that it is not something that is likely to create real clinical problems? In other words, the radiologists, the readers, and the local physicist, if there is one, would be able to spot it very quickly?

MS. **MARTIN:** You are going to spot it very quickly, right.

DR. KARELLAS: It is true that eventually, it will become obvious when an astute radiologist or technologist will discover it, however, the concern is that there will be certain studies that will be done, and the patient will be gone, and images may be suboptimal, so eventually, it will be found, it will not go for very long, but it is just that there may be something compromised, perhaps not of great significance, but certainly mammography may not be done at the state-of-the-art

evel.

MS. **HARVEY:** I have another question. **Do** you generally find a problem on the initial testing, or is this a problem that occurs over time, that you see that the detectors **go** out of whack on your annual when you come back, do you see problems at the annual testing, or **do** you see more problems at the initial testing?

MS. **MARTIN:** The initial testing is usually good. I think it is absolutely crucial, though, that it be tested, at least sampled, again cross-check some way for each one of those initially.

My experience is the installations are usually done very well now. I wouldn't say that was necessarily the case two years ago, being the installers have gotten much better, and I think part of that **is** because they are trying to make the criteria that has been set.

MS. **HARVEY:** **Dr.** Karellas.

DR. KARELLAS: The question that I have is what we should be doing when we have a brand-new machine and it has all these multiple modes, and we have not discovered how we are going to be using that machine, and the site needs to accept it.

If you accept only two or three or four modes, and then six months later, you discover that you want to use all the others, and you find something that doesn't work very well, then, it is more difficult to go back to say that that was not done properly in the beginning, especially post warranty.

So, it is somewhat of an issue as to whether we need to test absolutely everything upon installation, but that can be a very frustrating experience because you are testing something that may be so far out of the real application.

So, I still maintain that upon installation, the site should define certain modes of use and perhaps one or two or three above and beyond that based on how this machine should be used, and perhaps after the first or second year, you could perhaps narrow it down a little narrower to say that we are never going to use these modes, we are only restricted at just to these three modes.

MS. HARVEY: Dr. Pisano.

DR. PISANO: I have another question for the physicists. Isn't it the case also that your phantom testing on a weekly basis would suggest

:here is an AEC problem, you would see your OD :hanging over time even with the same settings?

I am trying to get a feel for how langerous this is for patients. My sense of this is that it is not very because of these two things, :hese clinical images will chance and the phantom imaging will change, so even if you don't check :very mode, even if they use it one or two, you are going to find it somehow. But I would like to hear your comments on that.

MS. MARTIN: Again, as long as you zross-check the modes, I don't think you are going to have a problem. I have not found it a necessity to check the complete thickness for every single mode, and, yes, the idea of if you wanted to extrapolate it for those instruments that have eight detectors, do you want eight phantom images every week to verify that you have consistency. You could take it to the nth degree and make the same requirement, and I don't think any of us want to go there.

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: I agree with Dr. Pisano. First of all, I do not feel it is dangerous and I feel very strongly that weekly phantom tests are

very good, and technologists, in fact, in most situations, it is technologists, that they call us about problems, and they are very vigilant about image quality.

On the down side is that if something ever might happen that shows okay on the 4.3 cm phantom, but it doesn't track very well when the thickness is 6 cm, that is possible, but at least in our experience, most of the time technologists call us and they say there is something wrong with my AEC, and interestingly, you may have tested it three months ago and everything was fine, and they alerted us.

So, what radiologists and technologists see every day is extremely critical.

DR. FINDER: One point that I would want to bring up in terms of the phantom testing, the phantom is one image taken under the clinical conditions for that thickness of breast, so you will not be checking or necessarily have any idea how the other submodes might operate in terms of the AEC.

In fact, depending on how a facility sets up its protocols, if it does, their standard patients, say, in the typical AEC mode, and not the

full auto mode, you won't have any idea what is going on with the full auto mode in terms of looking at the phantom.

But these are the issues that we would like discussed and try to come to some kind of consensus.

MS. HARVEY: Mr. Camburn.

MR. CAMBURN: Maybe I can just relay some of the information that we get from our inspectors from time to time about this, especially in terms of your fourth question that you ask here about testing submodes 1, 2, and 3, when submode 1 might only be used with a 2 cm thick breast and submode 2 with a 4 mm, and so on.

What we find from time to time is the technologists will inadvertently use the wrong submode especially if you have a number of technologists working with the same equipment, they don't all seem to be on the same page at the same time, plus there are patients whose size fall between 2, 4, and 6, and the technologist makes a judgment and may sometimes judge to use a different submode than what may have been initially assigned for that thickness.

So, we kind of like to see, although a

reasonable amount of testing, that the submodes are all tested.

MS. MARTIN: That is why I made the comment earlier. I think each of the submodes needs to be tested at least at some thickness to show that it tracks, but if all the submodes are tested--and I would add to Andrew's comment, we always test an 8 cm breast because at least in Southern California, we have several women that fall in that category--so, I think the 8 cm breast is absolutely critical to be tested.

Now, what I have found is for many of the 8 cm breasts, the 8 cm phantoms, it is necessary to adjust the density on some units to achieve the optimum density, and that option is nice to have, and I think that is part of the physicist's responsibility to give the facility a technique that will bring their large breasts into the same density range as their average breast. That is part of working with the facility.

As long as I have tested those modes over some part of the thickness and they all meet the tracking, I have not found a problem with testing every mode for every thickness.

MS. HARVEY: Dr. Pisano.

DR. PISANO: I guess I want to reiterate Melissa Martin's point about the cost to facilities of having machines down for longer periods of time than are needed.

I think the reason why I kept going back to the point of patient safety is I think that maybe one could make a case that at acceptance, all the modes and all the thicknesses should be tested and then maybe after acceptance, then, only the ones that are clinically used should be tested routinely.

In that way, I really think you are probably doing the maximum at the beginning and then you are not going to hurt patients or I want to also echo Andrew Karellas' point that the technologists are really right on top of those, when the AEC drifts out of calibration, we know about it pretty quickly, so I don't see that there is a practical real problem.

It is more because the regulations say it, you have to figure out how to do it problem. In reality, we are on top of this AEC, and we know when it is not working properly in clinically relevant modes. So, I feel like we should probably try to make it as supportive of the regulations,

but not hugely time-consuming for the facilities.

DR. **KARELLAS:** **I** think we should also realize that the way we are testing it, at the various modes and the various thicknesses, we are using Lucite, which is really a structureless material as far as x-rays are concerned, and the sensors, that is not what they see. They see very inhomogeneous density.

So, we can be testing some of these things forever and never really reaching perfection as far as matching it to the anatomy, and we must realize that. There is a point that when we go above and beyond, we get diminishing returns. We just do not get much better image quality.

I do not want to de-emphasize the importance of the proper exposure. There is no question that with film-screen, the correct exposure is one of the most critical aspects of a good mammogram, but I think it can be done without going far above what we are doing today on testing the AEC.

DR. **FINDER:** **I** just have an attempt at clarification here. Suppose a situation occurs where in the beginning, a full testing of all the equipment modes as best as possible was done for

the evaluation.

Then, the facility decides that they are only going to use, let's say, two of the submodes, contrast and let's say dose, whatever, and then you do your annual survey testing those submodes, but sometime after your survey they decide that they want to use a third submode.

In your opinion, would that require you coming back to retest before they could use it on patients?

MS. MARTIN: Not if you could actually give a cross-check, and I think that is where you would fall into the medical physicist oversight. What my advice to a facility would be is have the technologist on site shoot a phantom in both modes, and if they cross-check with each other, so you could calculate a dosage, and the dosages are reasonable and the technologist is trained to read out that phantom image, and so is the radiologist, if I get feedback that that is acceptable, that would be fine with me.

Frankly, as far as testing all those modes, what you find is for 6 and 8 cm, standard

only have to test contrast and standard, because

after about 6 or 8 cm, they are all going to pull the high kV and high filters anyway, there is not that much difference in them.

MS. **HARVEY:** Dr. Karellas.

DR. **KARELLAS:** This is one point that I am not sure I am in total agreement with Melissa Martin. Perhaps I don't understand or perhaps she has conducted some experiment on cross-modes, and there are some data that we should look at.

If, for example, we have tested something all in the contrast auto mode and somebody all of a sudden switches to the dose mode, we do have a very different situation in the equipment, and I am not certain that the system would behave the way that we would want to.

Now, I wouldn't be surprised if it does happen with certain machines and when you test it across all modes and somehow everything just clears through and everything is fine, but if I get a call as a medical physicist, and they ask me is it okay to do that, then, I would have to ask them to conduct the measurement.

But then they are performing a measurement that I should be performing, and we run into a gray area although theoretically, it is possible that

somebody can send you three, four images under these conditions that you prescribe and measure the optical density and generate a report and say that, yes, it actually does conform versus going there on a visit and checking it on your own.

MS. HARVEY: We have Question No. 2. I refer you to the document on AEC testing, the second page, at the bottom, which has to do with, "Since some or all of the AEC configurations may share key components or algorithms, is it reasonable to assume that the failure of one configuration immediately makes the other suspect unless the cause of failure in one configuration can be isolated as unique to that mode. In that case, only the manual mode could be used as back-up until repairs have been made.

"An example of an isolated configuration failure would be a system that incorporates separate AEC detectors for different image receptor sizes. If one detector fails and can be identified as the cause of failure, then the continued use of the AEC with other image receptor would be appropriate."

MS. MARTIN: I think that comes back to Dr. Pisano's point a while ago. If you have one of

these instruments with eight detectors, and suddenly you find out that one of these is off, it doesn't necessarily mean all of them are off if you can verify that you move it to a different unit and it performs fine, then, obviously, you make a note and post something that says one unit is not usable.

The same think would come down to the Siemens unit. You could very well have the large bucky fail or the small bucky fail, but you wouldn't necessarily fail both of them. Obviously, that can happen.

Frankly, I don't have any facilities that, as the physicist, I allow them to use the manual mode of exposure. If my AEC failed, they are down. There is no way we use a manual technique for anything, and I think that is your bigger--the idea that you are going to allow screen-film mammography in today's world to be performed with manual techniques is out of date.

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: I totally agree with Ms. Martin. There is no way that I could think of mammography going on in a facility, going on in an manual mode. If the AEC fails, they are down,

period.

I would be interested to know whether anybody really would do that, but we don't, and I think most of my colleagues would not allow that to continue, and I think most technologists would stop.

MS. HARVEY: Dr. Pisano.

DR. PISANO: Just to clarify, because I don't understand, may have misunderstood, you are not saying, however, like for the Siemens unit, where there are two separate AECs, if one of them was down, the big image detector, but the smaller, you would still go ahead and allow imaging with the smaller detector?

MS. MARTIN: Correct.

DR. PISANO: Okay, because that is the way we do it at our place, and it seems appropriate to me.

MS. HARVEY: Is this a frequent problem, that sensors go down?

MS. MARTIN: No, I don't hear it that often,

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: We have had several problems with AEC on several units. In some cases,

we identify them, and in some cases, the technologists would call us. When we say "frequent," it is not too frequent, but if you have 10, 20 or 25 mammography units, one of them, in two or three or four years, something will come up.

MS. HARVEY: Rather infrequent.

Dr. Pisano.

DR. PISANO: This is a question for the physicists. In my experience, the AECs tend to drift a little as opposed to totally failing, so you notice on your phantom that the OD is changing, either going up or going down. That is what you notice as opposed to it's not working at all and the clinical images are really terrible, it's really just a very gradual, is that correct, is that what generally happens?

MS. MARTIN: That has certainly been my experience, and that is why you do QC every week, and that is why you track those phantom images, and that is why you have PMIs on the machines, is to bring them back into your desired range.

MS. HARVEY: Any other comments on Question No. 2?

Actually, I think we have sort of answered No. 3 since we have talked about manual mode.

"In the event of AEC failure, the manual node may be used for up to 30 days while the AEC is being repaired." I sense that that is not what the panel is recommending.

MS. BUTLER: Could I ask a question from the floor?

MS. HARVEY: Certainly. I recognize Ms. Butler from the floor.

MS. BUTLER: This is Penny Butler from ACR.

I would just like to ask for clarification on the document that was provided. I think it may assist the discussion that is going on.

AEC failure, what exactly does that mean? Does that mean that it fails the physicist test or does it mean that it just doesn't work, because I think a clarification on that point may sort of influence how the discussion goes.

The other question is what is the definition of manual mode, because in the current guidance that is out there, there was a discussion of if the AEC performance fails one of the performance tests in full auto, it would be appropriate to temporarily use the fixed kVp AEC mode in order to continue operating.

I would like FDA's interpretation of how this plays into this discussion.

MS. HARVEY: Thank you.

DR. FINDER: I guess it plays into the discussion in the sense of as we are trying to get a handle on the fact that these units have multiple AEC modes, and if you can figure out that only one or two or three of these modes are affected by whatever problems is causing it to fail a test or to cause problems, but the other remaining AEC modes are not, then, obviously, you could continue to use those other AEC modes.

If all those fail, the regulations do allow a manual technique for up to 30 days. Again, that is the way the regulations were written, taking into account the guidance that were received at the time the regs were written.

But the facility certainly has flexibility in terms of if they have a functioning AEC that is within the limits, and they can have confidence that it is, they can use that if their other AEC modes fail, for example, the full auto mode fails in some manner, they could use the fixed kVp AEC mode and continue on that basis.

But you do raise a good question of how do

you know what it fails, what is the definition of failure. Obviously, there are multiple definitions here, and I think that they each raise their own issues.

There is the failure that occurs during the physics testing, and then there is the failure that occurs clinically when somebody suspects that there is a problem and what do they do in that case.

Generally, what obviously we would recommend is if they believe that there is a problem, they get their physicist and take a look and see what really is going on, so that they do have a better understanding of what is failing and what isn't.

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: In our experience, failure may be gradual, as Dr. Pisano described, you see some drifting and the technologists may catch that before anybody else.

The other mode of failure is when, on the annual testing, that it does not track with thickness, and we will notice that it is slightly off, and the other mode of failure is when you get a call from the technologists and they tell you

that something is just very erratic.

This is not unusual, that they will tell you that it works the first 30 minutes in the morning, or if I take an exposure 15 minutes after I turn the machine on, it doesn't work very well, and then it sort of behaves somewhat better. That is somewhat of an erratic mode, and the technologists pick it up.

On the other part about the AEC, this is an automatic mode, so switching to more conventional AEC, as Ms. Butler indicated, fixed kVp, automatic exposure control, this is a form of an automatic mode versus going all manual.

MS. HARVEY: Ms. Martin.

MS. MARTIN: I would totally agree with what has been said, that would be the first option, if one of the full auto, auto mode fails, you would go to the next level down, which is the manual section of the kV and target and filter.

Again, I would come back to that is why initially, we do check, at least cross-check for the phantom with all the modes and make sure all the modes are functioning properly, which certainly allows the facility that option, and if they lose the auto-auto mode, they can very well use the

phototimed mode, and that has already been checked out by the physicist and it is ready to go, and it won't take them down.

I don't consider the single auto mode as a manual technique. I was thinking of manual as totally manual where that technologist is setting the exposure.

DR. **FINDER**: That is the correct interpretation of that. **AEC** mode, the fixed kVp is an **AEC** mode, it is not a manual mode.

MS. **MARTIN**: Yes.

DR. **FINDER**: Let me also ask this, follow up with this. You do the cross-testing both on the initial equipment evaluation and during each of the annual physics surveys?

MS. **MARTIN**: Yes, I do.

DR. **FINDER**: If a physicist didn't do that, would you say that if they hadn't tested it during the annual physics survey, at least at the 4 cm cross-check level, that if the facility wanted to switch to one of those modes and it hadn't been tested, the physicist would have to come back out and do that testing before it could be used clinically?

MS. **MARTIN**: **If** they don't have the data

vailable to calculate a dose and image quality, some type of check I would think has to be made. I would think you would have to at least shoot a phantom.

Not all facilities have the 2, 4, 6 cm lucite to test, *so* you are either going to have to have a physicist on-site or some acceptable procedure previously outlined that the physicist is willing to accept.

That could be the medical physicist oversight is what I am coming back to. If you have checked it out, *so* that you say in the auto-auto mode typically pull a 26 kV, and your mAs is 143, and you shoot it in phototime at 26, and it shoots 145, that should be perfectly acceptable, but you do need that cross-check done before you are going to use it on a patient.

DR. FINDER: Just to clarify things, right now the regulations, as interpreted, as written, require that the physicist come on-site. What is being mentioned here is the possibility of doing this kind of remotely through physicist oversight, which would be a modification of what we have right now.

That is what you are proposing or

recommending or suggesting?

MS. MARTIN: Yes, I am suggesting.

DR. KARELLAS: I don't think this is unreasonable for providing a set of data for the physicists under specific conditions if it is needed remotely to advise the facility on something like that, on cross-checking, however, it raises the question whether the physicist should be doing one back-up mode on the annual inspection, because there are many physicists that they will do only one.

They will ask the facility, what do you use, and they will use contrast auto all the time, and they will evaluate the contrast auto, and that's it.

If the contrast auto does not work, then, you don't have any data on the other mode, so you don't have a back mode, so the option is to either have an evaluation done there, and you can tell them go ahead, you can switch to the other mode, we have the data and your other modes would work.

But the question is how do you know now that the other modes would work? If one mode doesn't, how can you assume that the other modes would work. In all fairness to the patient, we do

not know. So, somebody has to do something at that point.

Now, in the more real world, a technologist is going to tell me on the other side, I have been using contrast auto all the time, I am not going to switch now to select the kVp. With three or four technologists doing that, they are going to get all confused, so chances are they are going to tell me I am calling Service right now and we are stopping.

I think they would be very unwilling to just go and do all kinds of things because they would be afraid that they would be doing the wrong thing.

MS. MARTIN: I guess maybe I have got technologists that would have no problems with that. I think it strictly depends on the facility, and I think that has to be part of the medical physicist's understanding and agreement with that facility is when they are going to be called and what they allow the technologists to do.

MS. HARVEY: Have we completed?

DR. FINDER: I just want to clarify, in the fourth one, where I think we had already gone over this, about the testing of the 2, 4, and 6 cm.

I just want to clarify in my own mind the consensus or at least some of the comments were that you would test the 2, 4, and 6, but only at the submodes that were used at those levels. Is that correct?

MS. MARTIN: That would be my interpretation. I think that is the suggestion, that is certainly the training the technologists are given when they are given their clinical training, that it is never suggested that they use the dose mode for a 2 cm fatty breast. That is part of any technologist's understanding is the appropriate mode to select for the type of breast being examined.

DR. FINDER: Just again to clarify, let's say the contrast is used at the 2, and the standard was used at the 4, and then all of a sudden they wanted to use the standard at the 2, any additional testing required or no?

MS. MARTIN: It would depend on whether it is a new unit or a reevaluation unit. If I have checked it at 4, and it crosses its contrast at 2 and 4, and the standard crosses at 4, if they want to shoot standard at 2 and the techniques are reasonable, it is probably going to work.

It hasn't been my experience that that would necessarily be a problem.

MS. HARVEY: Any other comments?

DR. FINDER: I just wanted to check. Anybody from the FDA side have any questions that they would like asked, or any items? Speak now or forever hold your peace.

MS. HARVEY: Or any other members of the audience?

I refer you to the Modification Document No. 5, Guidance for Industry and FDA. There have been quite a few changes in this document, which has been out for a while now for use by individuals.

DR. FINDER: I just want to again bring what this document represents. It basically took the guidance that we had already issued on these items, and what we are trying to do is update and modify what needs to be changed. So, that is why you are looking at a lot of issues that deal with the same type of topics, such as accreditation and certification.

If anybody has any comments about the changes, these actually have already been published and are out to the public. They are up on our web

site. If anybody has any items that they would like to discuss, now is a good time to do it.

I would also mention that there is quite a long, new section dealing with full field digital units and their certification, and explaining what we are doing presently with those types of units.

MS. HARVEY: Does anyone see anything? Yes, Dr. Pisano.

DR. PISANO: I just wanted to talk a little bit about the digital requirement, the digital pages 32 through 37 or so, 40, I guess. This ties in with what I am going to talk about a little bit this afternoon, so I don't know if you want me to wait and talk then or you want me to talk now.

MS. HARVEY: Well, give me a hint.

DR. PISANO: There is a currently active clinical trial going on for which I am the PI, called the American College of Radiology Imaging or Digital Mammographic Imaging Screening Trial, otherwise known as D-MIST, and we actually have a fair amount of data at this point about what tests, you know, we have been doing the manufacturers' recommendation as is required under MQSA, under this law, plus we have data on other tests, plus we

have been doing it for quite a while. At this point, we have 19 open centers and the trial has been open since October of 2001.

So, we have a lot of information, and I would encourage the FDA to move forward on kind of looking at the data that exists and trying to perhaps pare down the requirements over what is in the manufacturers' documents or their user manual, whatever it is, whatever you want to call it.

I am concerned about spending a lot of time doing tests because we have always done them on film, they may not be appropriate for digital, and it is just that time is money and if we don't need to do it, we probably shouldn't have to do it.

The reason I bring this up, it is going to be presented publicly at RSNA, the Radiologic Site of North American meeting this November, and Martin Yaffe, out of the University of Toronto, is the PI of the quality control piece of the trial.

I feel that once this presentation takes place, there is going to be more pressure on FDA to kind of respond and maybe cut down the requirements, so I would like to see us kind of be proactive. I want to echo what Ken Crocker said from Fischer this morning in his public

announcement.

I would like to see us kind of have more specifics kind of and detailed recommendations for QC for digital as opposed to just what the manufacturers recommend. I think there are many reasons. It is in the interest of patients, I think, just because of the amount of time that we spend doing it does cost the facilities money. It is obviously in the interests of the facilities and people like me who run facilities to kind of try to keep the requirements to a minimum.

Understandably, they have kind of mushroomed into a big set of requirements because the companies just didn't want to leave anything out that the FDA might want them to put in, but I think we now have really kind of--1 am not prepared to discuss today in my talk what things should be cut out, but I know that we will have, you know, this thing hardly ever drifts or once in a blue moon drifts or never.

So, I just want to encourage the FDA to kind of perhaps talk to ACR. I am talking about the American College of Radiology Imaging Network, not the ACR mammography presentation program, now there is two separate entities, about what is

available, perhaps even to hear what Martin has to say before the talk in November.

DR. FINDER: Yes, we would appreciate any access we could get to that information as soon as possible.

DR. PISANO: There is actually a public meeting in Washington, D.C. Actually, it is in Arlington, Virginia, at the Ritz Carlton in Pentagon City in October of the American College of Radiology Imaging Network where I am sure we will all get a glimpse of the information. I can't say who is going to give a polished RSNA presentation at that meeting, but I am sure we are going to hear about this at that meeting.

So, I will inquire of the ACR Imaging Network folks if you all can be invited to listen. It is a public meeting, so you certainly are welcome to come to the public sessions and perhaps meet with Martin there and the other physicists.

All the physicists for all the sites will be present or at least they are all supposed to be present at that meeting, so I would expect a very useful amount of information, you know, you will be able to get a lot of interesting and useful information at that setting, so I would encourage

you to attend.

DR. FINDER: I do want to kind of put this into perspective. The regulations dealing with full field digital, when they were written, obviously, there weren't any digital units that have been approved yet. We took as has been stated before the conservative approach and said that without any data, we would rely on the manufacturer of the equipment to establish a quality control system that would be adequate for their unit.

I think the idea has always been that as more information became available and the ability to kind of standardize the quality control for these units was developed, that that is what would happen, but until we get enough data available, it is going to be difficult and as we just heard, there is some data that is going to become available soon and as soon as it is, we are going to certainly want to take a look at it and see if we can progress along that frontier.

Another issue that has to be kept in mind is that some of these digital units are quite different from each other and that the quality controls that might apply to one unit may not apply to another. That also is an issue and the ACRIN

study will be dealing with a lot of different units and hopefully will be able to provide us with enough information, so that we can start formulating the ideas for a standardized quality control system.

I am sure that this committee is going to be directly involved when that information becomes available and guiding us in terms of what we would require.

DR. PISANO: Just to follow up on that point, we will have data from D-MIST, as you mentioned, for manufacturers, so we will be able to compare the need for different tests for each manufacturer, a very rigorous quality control program centrally monitored also, which is one of the strong features of it.

It is a little stronger than what MQSA does because FDA's inspections are an annual snapshot of what happens. This is literally being monitored by central physicists every week, so we can watch for it because it is so important in the trial to be sure we have the highest quality images, because we don't want people to question our results at the end as has happened in other clinical trials.

We want to really be sure, and so this is being monitored very, very carefully by physicists every week, so I feel that we are going to have about as comprehensive data on this topic as you can get.

MS. HARVEY: Very good. Thank you.

Dr. Karellas.

DR. KARELLAS: There is no question that they did some mammography units very different from each other, and it will require different modules for physicists and technologists who are involved in that.

I find it somewhat more difficult when I deal with the manual that comes from the manufacturers although it is welcome that they have that, but I believe medical physicists will find it a lot easier if they have to deal with modules from an accrediting body, such as the American College of Radiology, and I believe that it is a lot easier to communicate, a lot easier to ask a question.

We can always call ACR for what we want or hopefully, they feel an obligation that they have to do it. Frankly, the companies are excellent and they will give you what you want.

I find it somewhat more difficult to have

to call each company to find each person, if I have a question or the particular book or the version, the accrediting body provides more of a centralized area that I can deal with, who feel absolutely obligated that they have to provide that information that I need.

So, if we work in that direction, and if manufacturers cooperate to provide the information they feel that is very important, that their systems need to be tested on, and that can be worked into a document that parallels the existing ACR guidelines that we have.

Let's not forget that quality in mammography, at least from the technical point of view, has been achieved to a large degree because of the uniformity that we are able to achieve in quality assurance through these manuals that radiologists, technologists, and physicists have, and we refer to them all the time.

MS. HARVEY: Thank you.

Any other areas for comments?

DR. FINDER: If nobody else has any questions about the guidance document per se, there are some other guidance issues that have come up, I just wanted to bring them to the committee's

attention.

MS. HARVEY: Hold one second.

Ms. Gilbert.

MS. GILBERT: I do have a question. This is Alisa Gilbert.

In the documentation here, under Breast Implants, I know that there is not a whole lot a written in this, and for a lot of the native patients that I work with, this is a new procedure that is being offered now, but I also know that there is not a whole lot of information when it comes to following screening after that on the remaining breast or even doing mammography with implant or not even implant, but other types of procedures have been done on tram flaps or some information like that.

I would like to see some documentation or additional information in this body written on that, as well, on the procedure and protocol that should be developed for that, just to include it. I know that it wasn't even included in this, it just said implant, but there is other procedures that are now being taken that haven't been.

Walking into the procedure and asking for follow-up, it is completely an unknown, and I just

hink that that might be something that might be rought to the attention.

DR. PISANO: Can I ask a question? I am a ittle confused about what you are talking about, .nd I just want a clarification. Are you talking bout women who have had implants placed)est-mastectomy for reconstruction purposes?

MS. GILBERT: Yes, and the follow-up for :hat. I know that in here, it just says, on page 53, there is a question, "Is there a specific amount of training or number of mammograms of breast implant patients that the technologist must perform under direction supervision prior to performing these studies?"

It is requiring that 40 hours initial training for that procedure.

DR. PISANO: I just have another question. I am not sure what extra procedure you may be referring to for patients who are ?est-reconstruction. I am not exactly sure. You said there are new procedures being offered, and I am not sure what you are referring to.

MS. GILBERT: I just see the notation here alternative requirements or breast implants. Implants aren't the only procedures that are being

done for women that have received mastectomies, and I was just kind of interested to know if that is going to be something that is going to be another addition to this, for women that do have just like one--maybe I am not posing my question or my concern clearly.

DR. FINDER: I think at the time that these regulations were written, there were two major issues that were being discussed, and I think chat the idea of the implants here was more the cosmetic implant use.

I think you bring up a very good point sbout additional training for patients that have undergone surgery and the correct procedures on how to do those examinations.

That is an issue we may be able to deal with in some way through guidance as a recommendation, but in terms of the regulations, what we have got is what we have got, but I do think that we do have the potential to expound a little bit on the guidance and deal with some of these other issues that you do bring up, and I think that is a possibility, and if not directly in our guidance, then, referring people to other sources where they can get the correct procedures

o do some of these patients, so I think that is a ery good idea.

MR. **GOODE:** I am Claude Goode from the tate of California.

I would like to relate a horror story. I ad a patient that complained of a breast ompression that had an implant, and the ompression ruptured the implant. The horror story as that the woman literally was screaming at the echnologist to release her, and she would not elease the compression. Evidently there was ignificant compression applied although the achine was within normal operating standards.

This patient has been left to suffer. 'here were no basic regulations that we could nforce, and I do believe that there is a need for 'DA or someone to at least come forth with some standards for the mammography of patients with reast implants. This needs to be discussed at ength and in depth, and presented somehow for the echnologists, the physician who is not present, nd this does present a major problem.

I would just like to relate that horror ;tory.

MS. HARVEY: Dr. Harrison.

DR. HARRISON: Miles Harrison. May I ask a similar question? This is someone with breast implants for cosmetic purposes, this is not post-mastectomy?

MR. GOODE: That is correct.

MS. HARVEY: Dr. Ikeda.

DR. IKEDA: This is Debra Ikeda from Stanford University.

I think we are talking about two different things here, I would like to clarify. That is a terrible story. I would like to first address the question about the post-mastectomy patient and the tram flap patient.

I think if I understand correctly, you were discussing patients who have undergone a mastectomy and have either had latissimus dorsi flap reconstruction or a tram flap reconstruction with autologous material from the abdomen, or patients, for example, who have a mastectomy and may have a small amount of residual tissue, and the recommendations for imaging that.

There are various amounts of scientific literature for stating that either it is not recommended, for example, there are some articles in which patients have had mastectomies and then

looked, they have tried to find out if there is a breast cancer recurrence, because that is what everybody is concerned about, and there is varying data on that.

Many places state that you should not be doing those patients routinely for screening, but if there is a lump, then, special views are often used for that, and every patient is so different, that I am not really sure that if there is a problem, that you can actually say that this is the right view to do or that is. Oftentimes, we have to come up with special views to address that specific patient's problem.

So, it is important when the technologist is initially trained in their 40 hours, for example, I think guidance is--correct me if I am incorrect--but guidance states that the technologist must learn all of the views, as well as patients who have implants, and they must be doing patients with implants under supervision, so they do them correctly.

I think we are talking about two different things.

DR. FINDER: Let me just correct one thing. The regulations do require that

technologists who qualify under the final regulations have some training in doing patients with breast implants. There is no requirement that they have to do a number of breast implant patients, though.

DR. HARRISON: I am in complete agreement with Dr. Ikeda, we are clearly talking about two separate populations here, and actually, the standard of care in our setting is such that we don't do imaging routinely of people post mastectomy with either autologous reconstruction or implants.

I guess I need to ask the question, are you referring to the training of the technologist to, in fact, be able to do mammography on women who have had cosmetic breast implants, are you addressing the training?

MS. GILBERT: I guess I am addressing both. I know in the native population, like Alaska Native specifically, that follow-up isn't recommended after that.

DR. HARRISON: Follow-up is not recommended?

MS. GILBERT: It's just unknown, it is just one of those unknown procedures, and because